Estimating "Reverse Payments" in Pay-for-Delay Settlements

Keywords: entry, collusion, patents, event-study.

Hashem Amireh

January 12, 2025

Abstract: *So called pay-for-delay deals have been the subject of scrutiny by regulators, courts, legal-scholars, and economists. However, the Supreme Court ruled that in order for a pay-for-delay deal to be anti-competitive, plaintiffs must demonstrate that there is a "large" and "unexplained" payment. However, many pay-for-delay deals have shifted away from cash payments towards business deals that heavily favor the generic entrant. Therefore, being able to estimate the value of these reverse payment deals is crucial. This paper proposes a method for estimating the value of these payments using event study abnormal returns.*

1 Introduction

Drug patents grant firms the right to retain exclusivity for a given drug. During the exclusivity period, such firms can extract monopoly profits for this drug. This creates an incentive for a brand drug firm to try to extend the exclusivity period for as long as possible.

In the United States, drug exclusivity is regulated by the Federal Drug Administration (FDA). All drugs approved (including those with tentative approval) are listed by the FDA in the so-called *Orange Book* along with the patents that are associated with them. Drug manufacturers may file several patents for a given drug even after it received FDA approval. For instance, Figure 1 shows three patents listed in the orange Book for the HIV drug Descovy which was developed and sold by Gilead. In a another example, the cancer Drug Imbruvica has 36 different patents listed in the orange Book. Note that a majority of these patents were filed *after* the drug had already been approved by the FDA.

While the FDA does make a determination regarding whether the patents requested to be added to a drug in the orange Book fall within scope of the Food Drug & Cosmetic Act, this determination is generally considered to be very permissive regarding patents being listed in the orange Book (Adler 2022). In the past year, the Federal Trade Commission (FTC)

Product No	Patent No	Patent Expiration
002	7390791	04/17/2025
002	7390791*PED	10/17/2025
002	8754065	08/15/2032
002	8754065*PED	02/15/2033
002	9296769	08/15/2032
002	9296769*PED	02/15/2033

Figure 1: Caption

has attempted to remedy this permissiveness by directly challenging around 400 drug "junk patents" by asking firms to withdraw these patents from the Orange Book or face litigation (FTC 2023; FTC 2024).

While the FTC directly targeting drug patents is a novel approach, generic drug manufacturers have been challenging drug patents for years. Passed in 1984, one the main goals of the Hatch-Waxman Act[1] was to combat the issue of weak drug patents by creating incentives for generic manufacturers to challenge patents they deem invalid. Potential generic entrants can challenge such patents claiming that they are either invalid or unenforceable. They can also assert that the patent would not be infringed.[2]

Following a challenge to a patent, the generic challenger(s) and the patent-holder can either let the courts adjudicate their dispute or enter a settlement. One "dimension" over which these settlements can be negotiated is *licensing agreements*, in which the patent holder allows the generic entrant to enter the market before the patent in question expires. Another dimension is *reverse payments*[3] from the patent holder to the generic challenger. Reverse payments can be direct transfers or indirect deal, which may include a variety of measures such as favourable manufacturing or marketing deals. Settlements with reverse payments are often pejoratively referred to at *pay-for-delay* agreements. Note that the details of such deals are not disclosed to the public and the settlement deals are often sealed. These so-called pay-for-delay agreements are viewed by some as anti-competitive since they allow the incumbent patent holder to maintain their monopoly and share monopoly profits with generic challengers even under a very-weak patent. Naturally, maintaining a monopoly likely translates to higher prices for consumers.

Such deals have been criticized as anti-competitive and argued to hurt consumers by

[1]Officially named the "Drug Price Competition and Patent Term Restoration Act."

[2]Consider, for instance, a secondary patent that pertains to the manufacturing process. A potential generic entrant may claim that they would use a different manufacturing process.

[3]The use of the word "reverse" comes from the fact that in patent settlement disputes, the patent holder is usually the recipient of the payment, not the payer as is the case here.

forcing them to pay monopoly prices for longer periods. Outside the context of patents, a deal in which a monopolist pays-off a potential entrant to stay out of the market would be considered collusive and illegal under most anti-trust and competition laws. However, adding the patents layer makes the legality of such deals more murky.

Consider a setting in-which such patent related pay-for-delay agreements are considered *presumptively legal* (i.e. such deals are considered automatically lawful and are therefore permitted). This creates the incentive for incumbent patent holders to file superfluous patents for a given drug well after its approval date and then enter pay-for-delay agreements with any potential challengers, effectively sharing some of the monopoly profits. Such deals may be considered legal even though they are clearly using patent settlement disputes as a guise for collusive anti-competitive agreements.

In an effort to curb possibly anti-competitive deals, the FTC has attempted to challenge such deals in court. This culminated in the 2013 United States Supreme Court *FTC v. Actavis*. The FTC argued that all generic patent challenge with any form of reverse payment should be considered presumptive illegal, which would have effectively closed the door for any future pay-for-delay deals. However, the Court ruled that deals containing a reverse-payment are neither preemptively legal nor presumptively illegal. Instead, the Court considered the uncertainty surrounding patent validity and ruled that the *rule of reason* must be applied on a case-by-case basis. This means that the FTC—or any other group seeking to challenge a deal—must individually litigate such deals to demonstrate that the anti-competitive effects of a given deal outweigh any "procompetitive" effects that might exist. This, however, can be very costly for taxpayers specially if the practice becomes wide-spread.[4]

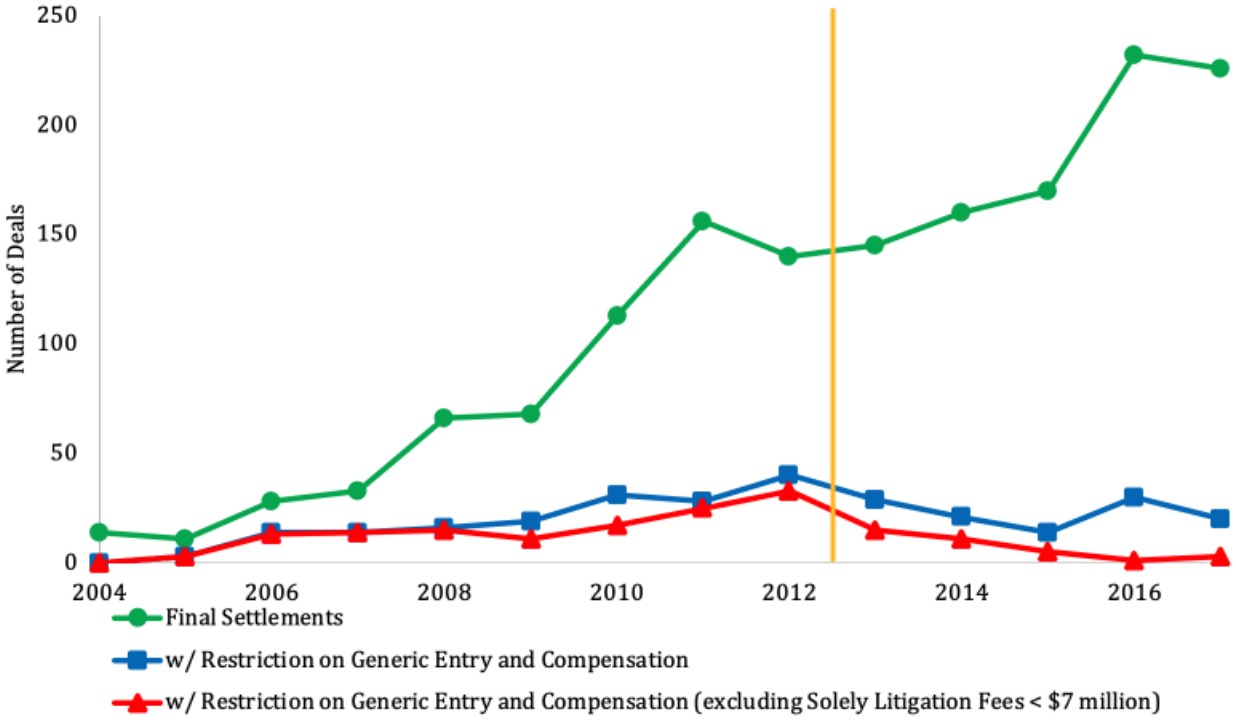
Furthermore, in its ruling, the Supreme Court stated that there needs to be an "unexplained *large* reverse payment" for a litigant to demonstrate that a settlement is indeed anti-competitive and therefore illegal. However, as reverse payment deals started facing more scrutiny, firms started moving away from cash reverse payments to less transparent business deals that provided favorable terms to the generic challenger (FTC 2020). I will call these "indirect reverse payments". By moving away from cash payments to business deals favoring the generic entrant, it becomes harder for the FTC to determine and demonstrate in court that such deals constitute "large and unexplained" indirect payments.[5]

Figure 2 shows generic challenge settlement deals evolved over time. The yellow line shows

[4]In response, the bipartisan U.S. Senate bill S.142 — 118th Congress (2023-2024) was introduced to ban such reverse payments while leaving in place the possibility to settle such disputes using licensing deals (i.e. early entry of the generic before the expiration of the patent). However, the bill never made it to the Senate floor.

[5]This is perhaps what drove the FTC to attempt the novel approach—mentioned earlier—of directly targeting patents it deems as invalid. If such efforts are successful, they would be able to prevent pay-for-delay deals from taking place to begin with.

Figure 2: Evolution of Generic Entry Settlement Deals (Data Source: FTC, 2020)



when the Supreme Court ruling was announced. While deals with cash compensations (red) trended down, deals with indirect reverse payments continued climbing (green).

Since preventing pay-for-delay deals requires the FTC to demonstrate that there exists a *large* "payment" in the form of a business deal that is favorable to the generic challenger, it needs determine or estimate the value/magnitude of such a deal. This is important for two reasons. First, it allows the FTC to determine which deals have the largest reverse payments which helps the FTC determine which deals to challenge given the limited resources.[6] Second, the FTC's estimate of the value of a reverse payment can be used to make their case in court. Therefore, estimating the value of obfuscated reverse payments in the form of business deals favorable to the generic challenger is important for preventing anti-competitive pay-for-delay deals that hurt consumers through monopoly pricing.

To my knowledge, there has not been any attempt in the literature to estimate the value of such deals. I propose a method for estimating such deals using the abnormal returns on stocks observed for firms that enter pay-for-delay deals. The method is by no means perfect but it intended as a first step towards the goal of reaching reliable estimates for reverse payments.

[6]Deals with the highest reverse payments are likely to be the most harmful for consumers. Furthermore, a the larger magnitude of reverse payment may lead to a stronger challenge.

The method relies on increases in the stock prices of the firms involved following the announcement of a deal. Typically, we observe an increase in the stock price for both the patent-holding brand firm as well as the generic challengers. This can possibly be attributed to the idea that through this deal, the firms are able to maintain monopoly pricing and share the profits between them. However, in order to be able to leverage this change in stock price following a deal, we need to account for the uncertainty that existed before the deal was signed. There are two important factors of uncertainty that exist before the deal is announced. First, there is uncertainty regarding whether a deal would be struck to begin with (as opposed to the case being adjudicated by a judge in court). Second, there is uncertainty about the likelihood the generic challenge to the patents succeeding if the case goes to court (i.e. the strength of the patents).

To that end, using a variety of data sources, I constructed a dataset containing both cases that were settled and cases that went to court. The constructed dataset includes case details, patent data, and medicaid drug spending on the drug overtime (as a proxy for drug revenue. I then estimate reverse payments in patent settlement cases by utilizing a model that incorporates these various factors including abnormal returns, patents' strength, settlement probability, and expected revenue differences under monopoly and competition. Some firms, particularly privately held ones, were excluded due to the lack of publicly available data necessary for the estimation.

To address the uncertainty regarding the likelihood of settling, I use a probit regression model to try to estimate the probability a deal would be reached based on the cases we observe in dataset (whether they are settled or adjudicated in court). Furthermore, I use a probit model to estimate patent strengths based on the cases that were adjudicated in court.

Even after settling, there remains uncertainty about how future profits could evolve (e.g. the possibility of further challenges). This is addressed by using a timeseries log-log profits model using the medicaid spending data.

The method used produces results that generally align with expectations, but it shows signs of imprecision. This imprecision arises from relying on Medicaid spending data instead of actual revenue data and from stock value fluctuations around settlement periods that are unrelated to the settlements themselves.

More critically, while the estimated reverse payments for brand firms appear reasonable, those for generic firms are significantly underestimated. This underestimation is likely due to the fact that rebates, which are not captured in the Medicaid data, make up a larger proportion of the brand-name drug prices than generic prices. As a result, the revenue estimates for generic drugs are too low, leading to an underestimation of their competition profits and downward-biased reverse payment estimates for generics.

Overall, while brand firms' reverse payments align with expectations, the estimates for generics are biased downward, making them statistically insignificant. This suggests that while the model offers useful insights, it requires refinement, particularly in the treatment of generic revenue data.

The paper is structured as follows: Section 2 discusses theoretical and empirical literature relating to pay-for-delay agreements. Section 3 describes the data collection process, including the compilation of a comprehensive dataset of patent dispute cases, relevant patent attributes, and drug revenue data. Section 4 presents the model developed to estimate reverse payments and patent strength, followed by Section 5, which details the estimation strategy and methodology. Section 6 discusses the results, offering insights into the magnitude of reverse payments and their implications for market competition and consumer welfare. Section 7 concludes.

2 Related Literature

There are several theory papers on this topic in the literature. Bokhari, Mariuzzo, and Polanski (2020) discuss the stability of such pay-for-delay deals and first-mover advantage. Similarly, Palikot and Pietola (2022) discuss pay-for-delay deals with conditions on future challenges and argue that banning pay-for-delay deals could reduce challenges and licensing deals, which could harm consumers. Ding and Zhao (2019) use a game-theoretic model to show that such deals may "increase ex-post competition under certain conditions" while also discussing the innovation implications. Manganelli (2020) discuss pay-for-delay deals under asymmetric information (with regards to patent strength).

Several papers have addressed empirical aspects of this topic. However, none have attempted to delineate licensing deals from payments. Bokhari (2013) uses a case study for ADHD medication to show how such deals lead to increased prices. Similarly, Helland and Seabury (2016) show that settlements lead to increased prices and reduced quantities. They also show that banning all settlements would lead to a marginally reduced research and development expenditures. Drake, Starr, and McGuire (2014) use an event study to show that patent settlements with pay-for-delay "indication" are associated with increased stock prices while those without do not. Jacobo-Rubio, Turner, and Williams (2020) use an event study to estimate the stakes for the generic manufactures and brand monopolists who engage in pay-for delay.

3 Data

Due to the nature of this paper, there is not a single dataset that provides all the data required to perform the analyses and estimation. In fact, much of the data had to be collected by manually. This section will describe the data collection process and all the data. It will also provide some summary statistics for the data collected.

3.1 Data Collection and Compilation

First, I collected data for two types of generic entry patent dispute cases: (1) cases that were *settled* out of court and (2) cases that were *adjudicated* in court. For the remainder of this paper, I will simply refer to these two types of cases simply as "settled cases" and "adjudicated cases".

The first step was to generate a list of potential cases of each type. To my knowledge, there does not exist a list of cases generic entry adjudicated cases that is publicly available. I was able to create list through two different methods. First, I used online searches for **news articles** using keywords like "patent", "generic", "drug", and pharmaceutical company names. This would provide a basic list of drugs and court decisions. I decided to limit my search to cases adjudicated by appeals courts in order to ensure that there is little uncertainty remaining following the ruling (appeals to the Supreme Court are exceedingly rare). I supplemented this search by also looking at cases using the **USPTO (2016) Patent Litigation Dataset** (which was not as helpful since it is impossible to do discern which are generic entry cases and which are not without looking at each case's court documents). I used the **DrugBank (2023) DataSet** in order to get a comprehensive list of pharmaceutical patents to be used filter for only pharma-related cases.

For settled cases, **Drake, Starr, and McGuire (2014)** provides a rudimentary list[7] of settled cases that they have collected. I used this list as the primary source for settled cases (with some omissions[8] and additions (based on article searches similar to the method used for adjudicated cases).

Once a list of cases of each type was compiled, it was then time to collect further data on each case. First, for adjudicated cases, I looked through **federal court documents on PACER (2023)** for each case in order to collect the following information: (1) date of

[7]List includes, drug name, generic name, announcement date, latest patent expiration date, and whether a reverse-payment is "indicated" in press coverage).

[8]Cases were omitted for a variety of reasons such as (1) a drug being over-the-counter which would make medicaid-spending on the drug an unreliable proxy for revenue, (2) cases being too old, or (3) in one case, the drug being withdrawn from the market by the FDA shortly after a settlement due to safety reasons.

ruling, (2) list of brand company(ies) involved[9], (3) list of generic challengers involved, (4) patent(s)-in-dispute, (5) how the appeals court ruled on each patent, and (6) whether the ruling affirmed of overturned the lower-court's ruling. I also used PACER court documents for settled cases to determine the patent(s)-in-dispute.

3.1.1 Patent Data

Each of either type usually contained more than one patent. For each patent, I used the **USPTO (2024) PatentsView** to collect general information about each patent such as title, abstract, number of citations, application date, approval date and other details. Further information about each patent was also collected from the **Unified Patents (2024) dataset**. This primarily includes proprietary measures of validity and value for each patent.

Interestingly, neither USPTO PatentsView nor UnifiedPatents data contain patent expiry dates. One solution is to use the patent application date and just add 20 years to it but that did not seem to be the case for some patents. Therefore, I used the **USPTO (2015) Historical Patent Data Files** which contained the contained the expiry date for *some* of the patents. I also scraped the expiry dates for each patent from **Google Patents (2024)**. Interestingly, it was not uncommon for these two sources to disagree on the patent expiry date (sometimes by several years). These dates were sometimes inconsistent with both the 'application date plus 20 years' method and with each other. When these dates were inconsistent, I manually looked up the **FDA ANDA Tentative Approval Letters**, which outline the patents the generic drug company may be infringing. These documents also included the expiry date for each patent listed.

Typically, a novel drug will have a "primary patent" which pertains to the active ingredient. However, drug manufacturers can file so-called "secondary" patents that pertain to a variety of things including manufacturing techniques, new uses, efficacy results, altered formulations, among others. Many of these patents are filed after the drug is approved by the FDA, which extends the exclusivity period of the drug beyond the initial patent's expiration.

Pharmaceutical patents can generally be categorized into one of five categories: (1) composition/active ingredient patents, (2) formulation patents, (3) process/manufacture patents, (4) method-of-use patents, and (5) combination patents. However, to my knowledge there is no dateset that specifies which category each pharmaceutical patent belongs to. However, one can relatively easily deduce what category a given patent belongs to by reading the patent title and abstract. I created a custom GPT on **ChatGPT** in which I provided definitions for each category of pharmaceutical patents (Amireh 2023). I was then able to

[9]It is not uncommon for one company to develop the drug and own the intellectual property while another company conducts human trials and handles production, labeling, and distribution of the drug.

feed the GPT the titles and abstracts of all the patents for it to categorize. I also randomly selected 30 patents to independently categorize myself. I then compared my classification of the 30 patents with those generated by the GPT and they matched perfectly.

3.1.2 Drug and Revenue Data

In lieu of expensive drug revenue datasets, I used Medicaid spending on each drug as a proxy for revenue, utilizing the **Medicaid State Drug Utilization Data** (CMS 2024). However, one of the drawbacks of this data is that drug name column and—to a lesser degree—the company name column are virtually unusable. I had to rely on NDCs (unique drug label identifiers); I had to identify all the NDCs for every drug-company pair in my data.

I therefore needed to supplement the SDUD data from the **NIH (2024)**[10] **RxNorm** which provided information such as drug names, generic names, and when the label was activated. I also used **HIPPASpace (2024) Data** as another source for drug information since it provided more specific names including dosage and administration method.[11]

Another issue that arose is that mergers and acquisitions are quite common in the pharmaceutical industry. Therefore, following a merger, a drug might be reissued under a new NDC. I did my best to manually track these issues and add any additional NDCs needed in such circumstances.

Since I am using Medicaid drug spending as a proxy for drug revenue, I also had to retrieve data on annualized U.S. drug spending provided by the **US Department of Health & Human Services (2022)** and inflation data from **FRED (2024)**.[12]

3.1.3 Firm and Stock Data

For the event study portion of the estimation, I needed to retrieve the stock data for each firm in my data around the date of the event. I used **CRSP (2024)**[13] **Data** for stocks listed on U.S. stock exchanges and **Compustat Data** for those listed on foreign exchanges (S&P 2024). For foreign exchange rates, I used the Wharton Research Data Services data complied from **Federal Reserve (2024) H10 reports**. Note that I had to manually figure out the applicable stock ticker for different firms to take into account circumstances like mergers and acquisitions.

[10] National Institute of Health

[11] This was necessary since sometimes the disputed drug was specifically a version that had a novel method of administration (e.g. Alprazolam Disintegrating Tablets which RxNav would simply list as Alprazolam).

[12] Federal Reserve Economic Data

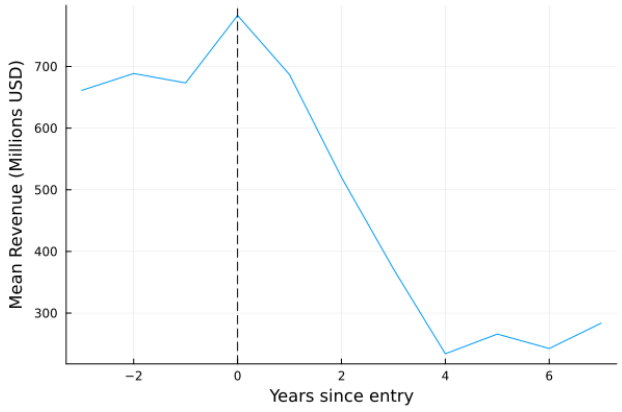
[13] Center for Research in Security Prices

3.2 Summary Statistics

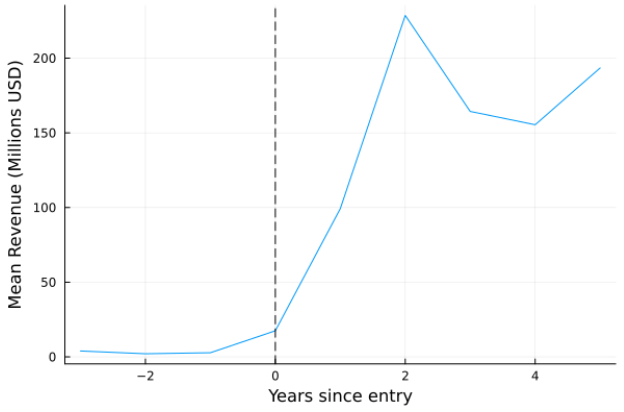
Table 1 provides comprehensive summary statistics regarding the cases data collected. Note that the patent strengths are estimated (see Section 5 for details). Figure 3 shows how revenue for brand manufactureres and generic challengers evolves after entry.

Table 1: Descriptive Statistics

	N	Sales ($ mil.)		Brand Volatility		Brand Mkt Cap ($ bil.)		Patent Strength (est.)		Patent Count		Active Ing. Patent Count	
		Mean	*SD*	*Mean*	*SD*	*Mean*	*SD*	*Mean*	*SD*	*Mean*	*SD*	*Mean*	*SD*
Total	52	814	1,235	1.65	0.99	0.384	1.85	0.22	0.19	2.46	2.07	0.19	0.53
Adjudicated	47	2,397	3,624	2.69	2.86	2.85	8.70	0.52	0.20	1.94	1.41	0.43	0.58
Brand wins	99	1,566	2,754	2.12	2.11	1.50	6.09	0.36	0.25	2.21	1.80	0.30	0.56
Brand loses	25	2,397	4,238	2.12	1.46	3.28	8.46	0.57	0.22	1.44	0.82	0.52	0.65
Mixed[14]	17	1,516	1,795	4.11	4.48	3.10	10.87	0.44	0.18	2.18	1.59	0.24	0.44
Settled	5	5,392	3,980	1.74	1.32	0.09	0.07	0.55	0.09	3.6	1.82	0.69	0.55



(a) Brand firms



(b) Generic firms

Figure 3: Medicaid spending before and after generic entry

4 Model

For a given case i, there exists B many incumbent patent-holding firm and G many generic challengers. Firms are denoted with the subscript $j \in \{b, g\}$, where the subscript $b \in \{1, ..., B\}$ denotes an incumbent patent-holding firm and $g \in \{B+1, ..., B+G\}$ denotes a generic entrant. Note that incumbent patent-holding firms and the generic entrants can either go to court or settle. For case i, let α_i denote the probability that the challenged patent(s) are upheld if challenged in court (i.e. α_i captures the patent's "strength). Let β_i denote the probability of a generic challenge being settled rather than adjudicated in court. Figure (4) shows an example of the timeline for a generic challenge. At $t = 0$, a patent that is *not* disputed expires while another patents that is supposed to expire at $t = T$ remains in place. Generic challengers believe that the second patent is not valid and would like to enter the market at $t = 0$. The period during which the brand maintains its monopoly is marked in red, while the period of generic entry is marked in green. In Figure (4a), the period in question is colored gray. If the case is adjudicated by a court and the brand wins the gray area becomes red (i.e. the monopoly is maintained). If the generic challenger(s) win, it becomes green and the generic entry occurs.

However, if the firms choose to, they can enter a settlement agreement that may contain one of both of:

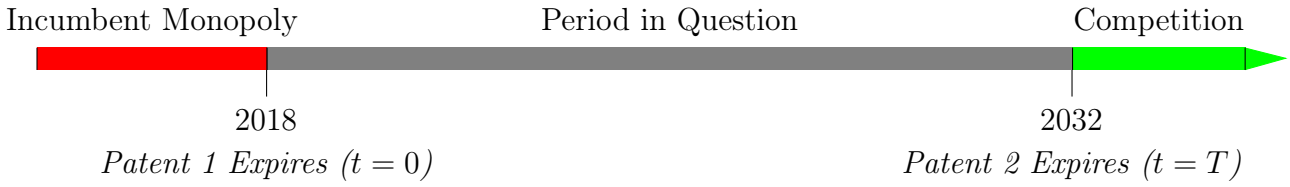
1. **Licensing agreement:** Patent holder can grant a licenses to generic challengers to manufacture the drug for $T - \tau$ periods of the remainder of the exclusivity period for drug i (i.e. generic challengers given licenses to start manufacturing the drug earlier than the patent expiry date). These licensing deals are illustrated in Figure (4b) as it splits the period in question.

2. **"Reverse payments":** R_i captures the value of all other measures which could include direct payments as well other business deals favorable to the challenger such as generous manufacturing contracts.

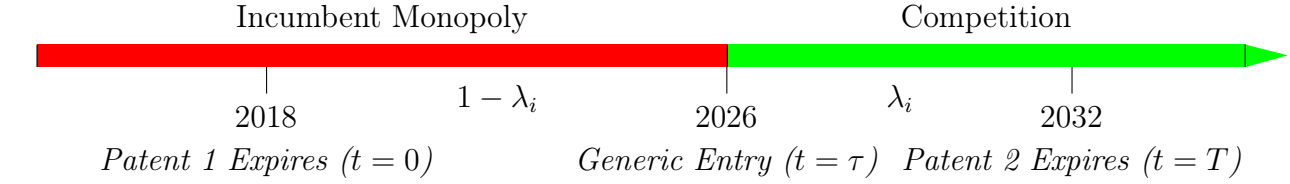
Given this setup, we can construct the following expected revenue expression for a given case-firm pair:

$$\mathbb{E}[\pi_{ij}^{pre}] = (1 - \beta_i)\alpha_i \pi_{ij}^{BW} + (1 - \beta)(1 - \alpha_i)\Pi_{ij}^{BL} + \beta_i(\mathbb{E}[\pi_{ij}^{\text{settle}} + R_{ij}]) \tag{1}$$

where BW and BL denote "brand win" and "brand loss" respectively. Note that if firm j is the "payer" of the reverse payment, R_{ij} would be negative. For the "payee", R_{ij} would be positive. Therefore, we generally expect R_{ij} to be negative for brand monopolists and positive for generic challengers.



(a) Period relevant to generic challenge



(b) Settlement outcome

Figure 4: Generic entry timeline

Once a settlement is reached, the uncertainty regarding the patent strength and whether a settlement would be reached (there is still uncertainty about the flow profits due to other factors such as other drugs entering the market or other possible future events). Once a settlement is announced, the expected revenue simplifies to:[15]

$$\mathbb{E}[\Pi_{ij}^{settlement}] = \pi_{ij}^{\text{settle}} + R_{ij} \tag{2}$$

By subtracting (1) from (2), we get the difference in expected revenue once a settlement is reached: $\mathbb{E}[\Delta\Pi_{ij}] = \mathbb{E}[\Pi_{ij}^{settlement} - \Pi_{ij}^{pre}]$. If we re-arrange the resulting expression, we get a closed form expression for the reverse payment R_{ij} as follows:

$$R_{ij} = \alpha_i \pi_{ij}^{BW} + (1-\alpha_i)\pi_{ij}^{BL} - \pi_{ij}^{\text{settle}} + \frac{\mathbb{E}[\Delta\Pi_{ij}]}{1-\beta_i} \tag{3}$$

Note that we use the assumption that the expected terms is equal to the realized deal.

Assumption 1 $\mathbb{E}[\pi_{ij}^{settle} + R_{ij}] = \pi_{ij}^{settle} + R_{ij}$

Therefore, if we can estimate $(\alpha_i, \beta_i, \mathbb{E}[\Delta\Pi_{ij}], \pi_{ij}^{BW}, \pi_{ij}^{BL}, \pi_{ij}^{\text{settle}})$, then we can use the closed form expression to estimate the reverse payment.

[15] Note the notational difference, $\Pi_{ij}^{settlement}$ includes the reverse payment while π_{ij}^{settle} does not.

5 Estimation Strategy

Estimating Patent Strength α_i

Using the portion of the data cases in the data that have been adjudicated, I specify a probit regression where the binary dependent variable representing the patent adjudication outcome (upheld vs. revoked) is regressed on patent attributes. Regression equation (4) provides the specification and Table (2) in the next section provides the results.

The parameterized regression can then be used to estimate the probability that other patents would be upheld if it were to go to court (i.e. patent strength). This employs an implied assumption in which we assume that that patents in cases that are settled are not markedly different from those that get adjudicated.

$$\alpha_i = \Pr[\text{brandWins}] = \Pr[\rho_0 + \rho_1 \text{patProcTime} + \rho_2 \#\text{citations/patAge} + \rho_3 \text{patentType} + \varepsilon_\alpha \geq 0] \tag{4}$$

Estimating Probability of a Settlement β_i

Since the data contains two types of cases (settled vs. adjudicated), I can specify a probit regression in which I regress the binary variable of attributes relating to case, drug, firms, and patents involved. Regression equation (5) outlines the specification used while Table (3) in the next section shows the results. With the parameterized model in hand, the probabilities of settling β_i can be estimated.

$$\begin{aligned}\beta_i = \Pr[\text{caseSettled}] = \Pr[&\rho_0 + \rho_1 \text{youngPatLifeRemain} + \rho_2 \#\text{citMostCitedPatAge} + \\ &\rho_3 \text{drugSpend} + \rho_4 \text{brandVolatility} + \rho_5 \text{brandMktCap} + \rho_6 \text{noActiveIngredPat} + \varepsilon_\beta \geq 0]\end{aligned} \tag{5}$$

Abnormal Returns: Estimating Difference in Expected Revenue $\mathbb{E}[\Delta\Pi_{ij}]$

In order to estimate the difference in expected revenues, I leverage an event study approach. This is based on the fact we often see an increase in the stock prices of all the firms involved in a generic-entry settlement deal, immediately following announcement. This can be attributed to the idea that once a pay-for-delay deal is entered, the firms can share monopoly profits amongst themselves even if the patents in question are week. It can also be attributed to legal fees as well as risk-averseness in investors' valuation function of a firm's revenue.

Assumption 2 *A change of* \$1 *in a firm's expected revenue is reflected as a* \$1 *change in its market capitalization.*

This assumption implies that changes in expected revenue are reflected one-to-one in the firm's market capitalization. Therefore, I can simply estimate the difference in expected revenue $\mathbb{E}[\Delta\Pi_{ij}]$ by using the "mean abnormal returns" from the event study and and multiplying it by the number of outstanding shares:

$$\mathbb{E}[\Delta\Pi_{ij}] = MAR_j \cdot \#shares_j \tag{6}$$

Using a standard "Market Model" for abnormal returns (JAFFE and WESTERFIELD 1985). First, I estimate the model using an estimation period that precedes the event:

$$r_{jt} = \rho_{1j} + \rho_{2j} r_{mt} + \varepsilon_{jt} \tag{7}$$

Then I can use the parameters to estimate the abnormal returns for the event period:

$$AR_{jt} = r_{it} - (\rho_{1j} + \rho_{2j} r_{mt}) \tag{8}$$

The mean abnormal return for a given firm j is:

$$MAR_j = \frac{1}{T} \sum_{t=1}^{T} AR_{jt} \tag{9}$$

Estimating Profits

In order to estimate what flow profits ($\pi_{ij}^{BW}, \pi_{ij}^{BL}, \pi_{ij}^{\text{settle}}$), I will rely on a time-series model to capture how profits are likely to evolve over time under different circumstances. For the purpose of this field-paper, I use Medicaid drug spending (SDUD data) as a proxy for drug revenue. I do this by multiplying the drug spending ratio of total US drug spending to medicaid drug spending in a given year. This comes with some pitfalls, namely, SDUD data[16] does not include medicaid rebates which are transfers from drug manufacturers back to medicaid. The rebates as a percentage of the sticker drug cost can vary across drugs and across different manufacturers for the same drug. Furthermore, another issue that may arise is that medicaid subscribers might have different consumption patterns than all drug consumers including privately-insured and non-insured ones. While these issues are critical enough that the results may be imprecise, this data can be replaced with actual revenue data

[16]Note that I adjusted spending for inflation.

(e.g. SSR Health Data) for more precise estimates. However, for the scope of this field-paper I rely on SDUD that may be imprecise but can still serve as a proof-of-concept.

For the estimation, I use two similar but slightly different log-log time-series models: one for brand firms (10) and one for generic firms (11). The results can be found in the next section in Tables 4 and 5. The indicator functions in the regressions are meant to capture the substantial revenue change following generic entry. However, while the revenue change is somewhat sudden, it takes a couple of years for the change to take place as show in Figure (3). Note that the generic revenue also takes into account the revenue of the brand firm from the same drug right before entry. With these time-series models parameterized, we can now estimate flow profits ($\pi_{ij}^{BW}, \pi_{ij}^{BL}, \pi_{ij}^{\text{settle}}$).

$$\log \pi_{bt} = \rho_0^b + \rho_1^b \log \pi_{b,t-1} + \rho_2^b \mathbf{1}_{\text{entry}_{t-2}} + \rho_3^b \mathbf{1}_{\text{entry}_{t-3}} + \rho_4^b \mathbf{1}_{\text{entry}_{\leq t-4}} + \varepsilon_{it} \tag{10}$$

$$\log \pi_{gt} = \rho_0^g + \rho_1^g \log \pi_{g,t-1} + \rho_2^g \mathbf{1}_{\text{entry}_{t-1}} + \rho_3^g \mathbf{1}_{\text{entry}_{\leq t-2}} + \rho_4^g \log \pi_{b,\text{entryYear}} + \varepsilon_{it} \tag{11}$$

Once these time series models are estimated, we can then estimate how flow profits are likely to evolve under the three different scenarios: brand wins, generic wins, and settlement is reached.

For the brand firms, if the brand wins, then we expect monopoly flow profits to continue for the full period:

$$\pi_{ij}^{BW} = \sum_{t=1}^{t=T} \pi_{bt}^{BW} \tag{12}$$

where π_{bt}^{BW} evolves based on (10). Notice, that all the indicator functions are equal to zero in this case.

Similarly, if the brand loses, then we expect profits to start going down:

$$\pi_{ij}^{BL} = \sum_{t=1}^{t=T} \pi_{bt}^{BL} \tag{13}$$

where, again, π_{bt}^{BL} evolves based on (10). Notice, that the indicator coefficients for the indicator functions will now have an effect. For instance, in period $t = 1$ profits will go down by ρ_2^b.

When settlement is reached,

$$\pi_{ij}^{\text{settle}} = \sum_{t=1}^{t=\tau} \pi_{bt}^{BW} + \sum_{t=\tau+1}^{t=T} \pi_{bt}^{BL} \tag{14}$$

Here the first term captures the profits based on the year that a monopoly is maintained under the deal while the second term captures the profits once entry occurs under the licensing deal.

6 Results and Discussion

6.1 Regression Results

Table 2 shows the results for the probit regression used to estimate a given patent's strength α. Processing time of the patent (i.e. time from patent application to approval) is correlated with patent strength. This could be because more complex patents take longer to approve but may also be stronger. Patent type is also a predictor of patent strength. In this regression, patent type is treated as a categorical variable, with 'active ingredient patent' as the reference level. Note that all other types of patents are associated with lower patent strength. This is expected since active-ingredient patents are generally considered to be the strongest and most pay-for-delay deals are usually related to other types of patents that generic manufacturers perceive as unfounded.

Table 3 shows the results for the probit regression used to estimate the likelihood of a case being settled. The "remaining life" on the youngest patent for a given drug is associated with a higher likelihood of settling. This could be explained by the idea that if more life remains on the drug's patents, the brand firm has a greater incentive to reach a settlement deal to guarantee monopoly profits for longer. In other words, the opportunity cost of losing is larger when there is significant exclusivity time left. Drug Medicaid spending is associated with a decrease in the likelihood of settling. This result might be surprising to some since the opportunity cost of losing a case for a higher-revenue drug might be higher creating more incentive to settle. That said, although statistically significant, coefficient for this regressor remains small (-0.002 per $1 mil. increase). Interestingly, an increase in the volatility of the brand's stock reduces the likelihood of settlement being reached. This could be explained by the idea that a high stock volatility is associated with financial challenges for a firm. If a firm is facing financial challenges, it might be unable to afford a large reverse payment needed to reach a settlement. A strong predictor for likelihood of settling is if an "active ingredient" patent is absent. This can be explained by the idea that without an active ingredient patent, the likelihood of winning an adjudicated case is smaller incentivizing the brand firm to settle.

Table 2: Estimation of patent strength α

Variable	Brand Wins
	Probit
Intercept	0.457
Reference group: Active-ingredient patent	(0.384)
Processing Time	0.210*
	(0.087)
Number of Citations / patent age	-9.864
	(7.092)
Method-of-use Patent	-0.990*
	(0.413)
Combination Patent	-1.294*
	(0.613)
Formulation Patent	-1.412**
	(0.456)
Process Patent	-1.464*
	(0.592)
Observations	95
Pseudo R^2	0.255

Tables 4 and 5 show the results for the time series regressions used to estimate the flow profits. The goal of the exercise is to generate an estimate of ex-ante flow profits before that takes into account the investors expectations regarding possible new drugs entering the market or possible new generic challenges.

Figure 5 shows the event abnormal returns following a settlement for settlements that have a reverse payment indication as well as settlements without indication, using Drake, Starr, and McGuire (2014)' categorization.

Table 3: Estimation of likelihood of settlement β

Variable	Dispute Settled
	Probit
Intercept	0.179
	(0.496)
Youngest patent life remaining (years)	0.110**
	(0.039)
# Citations for most cited / patent age	-18.414
	(9.566)
Drug medicaid spending ($ bil.)	-0.237*
	(0.102)
Mean brand volatility	-0.302*
	(0.122)
Mean brand Mkt Cap ($ bil.)	-0.103*
	(0.051)
Has no "active ingredient" patent	0.594
	(0.367)
Observations	99
Pseudo R^2	0.489

6.2 Estimated Reverse Payments

With the estimates for $(\alpha_i, \beta_i, \mathbb{E}[\Delta\Pi_{ij}], \pi_{ij}^{BW}, \pi_{ij}^{BL}, \pi_{ij}^{\text{settle}})$ in-hand, (3) can be used to calculate an estimated reverse payment for each case-firm pair. However, there are a few things to consider. First, there are usually multiple patents for every case/drug. I have chosen the strongest patent's strength to be used in *alpha* since entry requires all the patents to overturned and the strongest patent is the least likely to be overturned. Furthermore, note that some firms are privately held and therefore had to be excluded since $\mathbb{E}[\Delta\Pi_{ij}$ cannot be estimated using event study abnormal returns. Another issue that came up with one case (Nexium) is that it is an over-the-counter drug. This led to very low spending figures in the SDUD data and that drug/case had to be excluded.

Figure 6 shows the resulting estimated reverse payments for every case-brand firm pair

Table 4: Time-Series for Brand Firms Revenue

Variable	$\log \pi_{B,t}$
Intercept	0.998*
	(0.486)
$\log \pi_{B,t-1}$	0.936***
	(0.024)
$\mathbf{1}_{\text{entry}_{t-1}}$	-0.813
	(0.695)
$\mathbf{1}_{\text{entry}_{t-2}}$	-2.021**
	(0.745)
$\mathbf{1}_{\text{entry}_{\leq t-3}}$	-1.165**
	(0.438)
Observations	516
R^2	0.779

plotted against the brand's annual revenue[17] from the drug before the settlement. The red dots show settlements that Drake, Starr, and McGuire (2014) categorized as having a "reverse payment" indicated due to media coverage while the blue dots are settlements in which it was unclear whether there was a reverse payments (i.e. "no indication" of a reverse payment). Note that since the brand is the "payor" in a reverse payment, we expect the payments to be negative for them. As can be seen in the graph most of these payments are indeed negative but there are a few that are positive. Of those that are positive, almost all of them do not have a reverse payment indication.

If we focus on those that are negative, we see that the reverse payment magnitudes are within reason given the annual revenue of the drugs before the settlement. Note that Lipitor/Caduet appears to be an outlier. However, the reason behind this is because these cholesterol drugs are some of the highest revenue drugs ever. Furthermore, the estimated patent's strength for this drug was particularly high leading to a lower willingness to pay a large reverse payment.

While the method seems to produce results in the expected direction, there are clear signs of imprecision. This imprecision can be attributed to the issues mentioned earlier regarding

[17]This is actually the scaled and inflation adjusted SDUD spending).

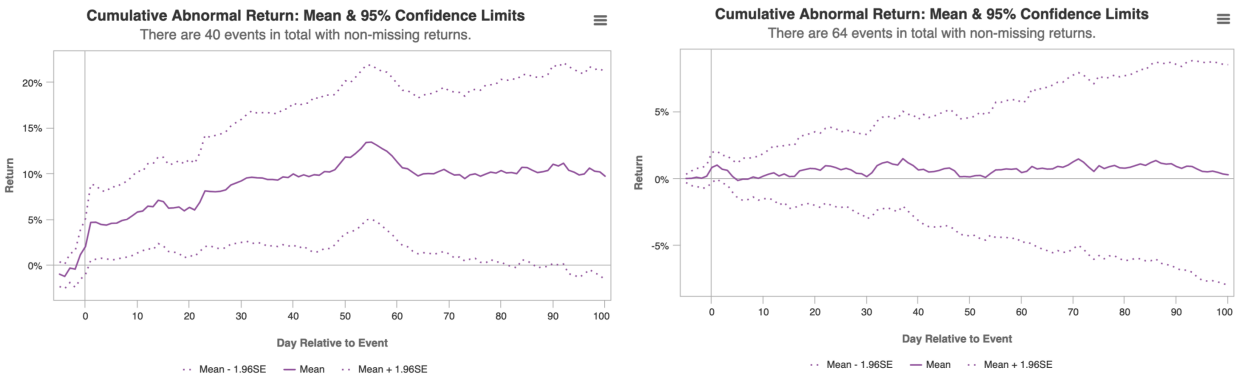
Table 5: Time-Series for Generic Firms Revenue

Variable	$\log \pi_{G,t}$
Intercept	-6.845*
	(2.727)
$\log \pi_{G,t-1}$	0.824***
	(0.025)
$\mathbf{1}_{\text{entry}_{t-1}}$	2.895*
	(1.329)
$\mathbf{1}_{\text{entry}_{\leq t-2}}$	0.601
	(1.437)
$\log \pi_b$ During Settlement Year	0.462**
	(0.144)
Observations	543
R^2	0.723

the use of SDUD medicaid spending data in lieu of actual revenue data. Another concern has to do with changes in the stock value around the period of settlement due to reasons unrelated to the settlement itself. A glaring example of this is the Valtrex settlement involving generic drug manufacturer Ranbaxy, which as shown in Figure 7, is clearly an outlier. The estimate of the reverse payment based on our model is $2.2 bil. which is far higher than the rest of the estimated generic reverse payments. The reason behind this is because around the same period, Ranbaxy's stock jumped considerably due to other news relating to an open criminal investigation into the company.

More importantly, while the magnitude of the reverse payments for the brand firms seems reasonable. It is clear that the magnitude of the reverse payments for the generic firms is far too low as shown in Figure 7. This is almost certainly due to the fact that rebates (which are not accounted for in the SDUD data) constitute a much higher percentage of the brand-name drug sticker price than they do for generic. This means that when using SDUD data to extrapolate the actual revenue for the drugs, the scaling factor is actually too small leading to generic drug revenues to be severely underestimated. This leads to π_{ig}^{BL} for the generic that are too small and to their reverse payments being biased downward.

Table 6 shows the means of the reverse payment for brands and generics and confidence



(a) With indication (b) Without indication

Figure 5: Stock returns for settlements with and without indication of reverse payment

intervals based on a bootstrapping procedure. Brand reverse payments that have been categorized by Drake, Starr, and McGuire (2014) as having a "reverse payment indication" have a statistically significant negative value that is consistent with our expectation. Due to the downward bias in the reverse payments estimates for generics, they are statistically insignificant.

Figure 6: Brand Reverse Payment Estimates and Brand Drug Revenue

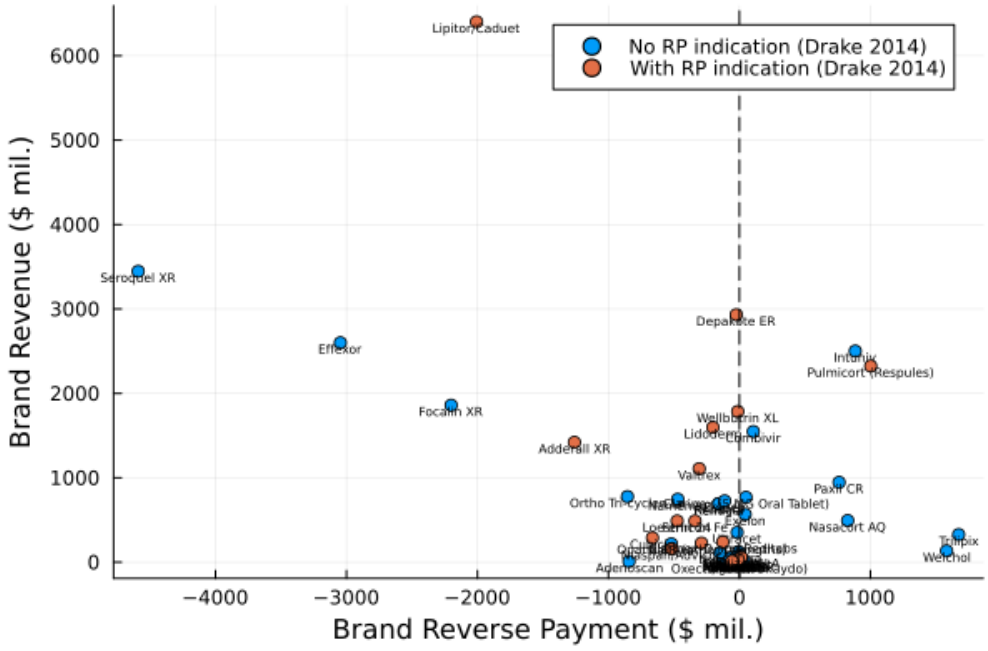
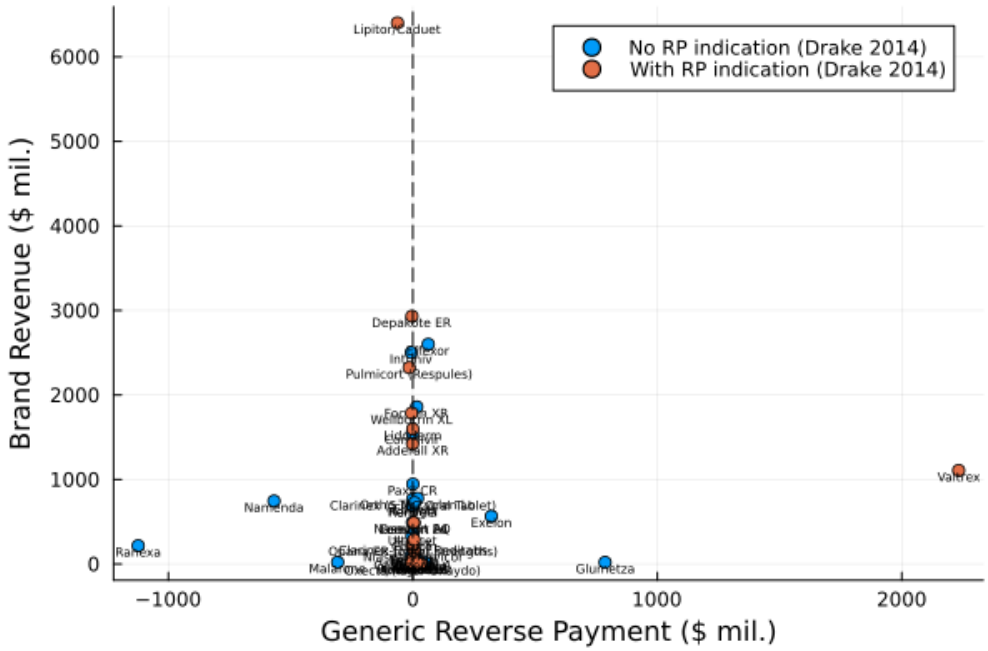


Table 6: Estimated Reverse Payments ($ mil) w/ Bootstrapped CIs

	Mean	*SE*	*95% CI*
Brand	-237.8	130.5	(-493.5, 18.2)
w/ reverse payment indication (Drake 2014)	-282.0	132.8	(-542.1, -21.6)
w/o reverse payment indication (Drake 2014)	-213.8	187.6	(-548.8, 184.5)
Generic	30.9	56.2	(-79.3, 141.2)
w/ reverse payment indication (Drake 2014)	129.9	127.5	(-119.9, 379.8)
w/o reverse payment indication (Drake 2014)	-23.4	50.0	(-115.3, 81.1)

Figure 7: Generic Reverse Payment Estimates and Brand Drug Revenue



7 Conclusion

This paper presents a novel approach to estimating the value of reverse payments in pay-for-delay agreements by leveraging event study abnormal returns and various patent and market characteristics. The analysis reveals that while the estimated reverse payments for brand-name firms align with expectations and demonstrate some consistency with the firms' annual drug revenues, the precision of these estimates remains a challenge. In particular, the estimates for generic firms tend to be biased downward, which highlights the need for further refinement in the estimation process.

Another possible refinement is to relax Assumption 2 which states that the change in expected revenue before and after a settlement matches the change in market capitalization for the firm. This can be done by adding a factor parameter (which I assumed to be equal to

one) that can be estimated using an event study where we observe both the changes revenue and market capitalization. A well-defined event here could, for instance, be the change in stock prices before and after earnings announcements since we observe the change between what the Earnings per Share (EPS) forecasts before the announcement were, and the realized EPS after yhe announcement.

Future research should consider integrating advanced natural language processing (NLP) models to enhance the accuracy of patent strength estimation. NLP models could be particularly useful for analyzing the textual data from patent documents and legal rulings to provide more nuanced insights into the potential validity and enforceability of patents. Additionally, the likelihood of settlement in patent disputes could be further enriched by incorporating a Nash bargaining model. This would allow for a more comprehensive analysis of the strategic interactions between patent holders and generic challengers, potentially offering a more robust estimation of settlement outcomes. Overall, while the methods employed in this paper provide valuable insights into the dynamics of pay-for-delay agreements, there remains room for improvement. By adopting these advanced methodologies, future work can contribute to a more accurate and comprehensive understanding of the economic implications of these agreements on market competition and consumer welfare.

Appendix A: Patent Categorization Using Custom GPT

OpenAI's ChatGPT allows for 'custom GPTs,' enabling users to create GPTs that, while still based on the ChatGPT large language model, behave differently for specific purposes. These GPTs can vary in complexity: anything from simple instructions and workflows to complex API integrations and proprietary data sources (OpenAI 2024).[18]

Since the type of drug patent is generally considered a strong predictor of a patent's validity (with composition/active-ingredient patents being considered the most valid), it was important to have information about what category each patent in my dataset falls into. However, there does not exist, to my knowledge, a dataset categorizing drug patents, into the five categories.

Therefore, I created a simple GPT[19] to categorize drug patents into the common drug categories outlined in 21 U.S.C. 355 of the Food Drug & Cosmetic Act, and made it publicly available. The GPT is able to read the titles and abstracts of a list of patents and categorize each of them accordingly. The user can either provide a typed list or a CSV table. To test the accuracy of this GPT, I randomly selected 30 patents and categorized them independently. I then compared my classifications with those generated by the GPT, and they matched perfectly.

Here are the instructions that were provided to initialize the GPT:

```
As a GPT specialized in categorizing drug patents, your role is to
analyze a list of drug patents provided by the user. Use the patent
title and abstract provided by the user to determine which of the
following categories each patent falls under:

1. Composition Patents: These patents protect the active
pharmaceutical ingredient (API) itself-the core chemical or
biological substance responsible for therapeutic effect of the
drug.
2. Method-of-Use Patents: These patents protect specific uses of a
drug for treating a particular condition or disease. Even if the
drug itself is not new, discovering a new use for it can be patentable.
3. Formulation Patents: These cover the composition of the final
pharmaceutical product, including the combination of the active
```

[18]More information can be found at https://openai.com/index/introducing-gpts/

[19]The GPT can be found at https://chatgpt.com/g/g-mDjPRNYjJ-patent-classifier

ingredient with other substances (excipients) to form a stable and effective medication. Formulation patents can also include innovations in the delivery mechanism of a drug, such as controlled-release technologies.
4. Process Patents: These cover the methods and processes involved in manufacturing the active ingredient or the final pharmaceutical product. This can include synthesis routes, purification methods, or any novel manufacturing techniques that offer advantages over existing processes.
5. Combination Patents: These patents protect drugs that comprise a combination of active ingredients. Combination patents are crucial when two or more known drugs are used together to achieve a synergistic effect, offering a new therapeutic option.

You should present your analysis in a table format, including the patent number and its corresponding category based on the description given by the user. If the information provided is insufficient to make a determination, ask for more details or clarify which aspects of the patent are unclear. Your responses should be informative, precise, and structured, assisting users in understanding the categorization of their patents.

References

Adler, Rachel Sachs; Marta Wosińska; Richard G. Frank; Loren (2022). *The FDA could do more to promote generic competition: Here's how*. [Online; accessed 24. Aug. 2024]. URL: https://www.brookings.edu/articles/the-fda-could-do-more-to-promote-generic-competition-heres-how.

Amireh, Hashem (2023). *Patent Classifier GPT*. Last accessed: August 21, 2024, https://chatgpt.com/g/g-mDjPRNYjJ-patent-classifier.

Bokhari, Farasat (2013). "WHAT IS THE PRICE OF PAY-TO-DELAY DEALS?" In: *Journal of Competition Law and Economics* 9.3, pp. 739–753. URL: https://EconPapers.repec.org/RePEc:oup:jcomle:v:9:y:2013:i:3:p:739-753..

Bokhari, Farasat, Franco Mariuzzo, and Arnold Polanski (May 2020). "Entry limiting agreements: First-mover advantage, authorized generics, and pay-for-delay deals". In: *Journal of Economics &amp Management Strategy* 29.3, pp. 516–542. DOI: 10.1111/jems.12351. URL: https://doi.org/10.1111/jems.12351.

Center for Research in Security Prices (2024). *US Stock Databases*. Last accessed through WRDS: January 19, 2024, https://wrds-www.wharton.upenn.edu/pages/get-data/center-research-security-prices-crsp/annual-update/stock-security-files/daily-stock-file/.

Centers for Medicare Medicaid Services (2024). *State Drug Utilization Data*. Last accessed: February 24, 2024, https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/index.html.

Ding, Yucheng and Xin Zhao (Dec. 2019). "Pay-for-delay patent settlement, generic entry and welfare". In: *International Journal of Industrial Organization* 67, p. 102532. DOI: 10.1016/j.ijindorg.2019.102532. URL: https://doi.org/10.1016/j.ijindorg.2019.102532.

Drake, Keith M., Martha A. Starr, and Thomas G. McGuire (May 2014). "Do "Reverse Payment" Settlements Constitute an Anticompetitive Pay-for-Delay?" In: *International Journal of the Economics of Business* 22.2, pp. 173–200. DOI: 10.1080/13571516.2015.1045744. URL: https://doi.org/10.1080/13571516.2015.1045744.

DrugBank (2023). *DrugBank Drug Data*. Last accessed: December 29, 2023, https://go.drugbank.com/releases/latest.

Federal Reserve (2024). *Foreign Exchange Rates - H.10*. Last accessed: March 18, 2024, https://www.federalreserve.gov/releases/h10/hist/.

Federal Reserve Economic Data (2024). *Inflation, consumer prices for the United States*. Last accessed: April 28, 2024, https://fred.stlouisfed.org/series/FPCPITOTLZGUSA.

FTC (2020). *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*. Tech. rep.

FTC (Nov. 2023). *FTC Challenges More Than 100 Patents as Improperly Listed in the FDA's Orange Book*. [Online; accessed 21. Aug. 2024]. URL: https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book.

— (Apr. 2024). *FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs*. [Online; accessed 21. Aug. 2024]. URL: https://www.ftc.gov/news-events/news/press-releases/2024/04/ftc-expands-patent-listing-challenges-targeting-more-300-junk-listings-diabetes-weight-loss-asthma.

Google Patents (2024). *Google Patents*. Last accessed: April 12, 2024, https://patents.google.com/.

Helland, Eric and Seth Seabury (2016). "Are Settlements in Patent Litigation Collusive? Evidence from Paragraph IV Challenges". In: 22194. URL: https://EconPapers.repec.org/RePEc:nbr:nberwo:22194.

HIPPASpace (2024). *HIPPASpace API*. Last API retrieval: April 1, 2024, https://www.hipaaspace.com/medical_web_services/medical_coding_web_services.aspx.

Jacobo-Rubio, Ruben, John L. Turner, and Jonathan W. Williams (May 2020). "The Distribution of Surplus in the US Pharmaceutical Industry: Evidence from Paragraph iv Patent-Litigation Decisions". In: *The Journal of Law and Economics* 63.2, pp. 203–238. DOI: 10.1086/707407. URL: https://doi.org/10.1086/707407.

JAFFE, JEFFREY and RANDOLPH WESTERFIELD (1985). "The Week-End Effect in Common Stock Returns: The International Evidence". In: *The Journal of Finance*.

Manganelli, Anton-Giulio (Oct. 2020). "Reverse payments, patent strength, and asymmetric information". In: *Health Economics* 30.1, pp. 20–35. DOI: 10.1002/hec.4174. URL: https://doi.org/10.1002/hec.4174.

National Library of Medicine (2024). *RxNorm API*. Last API retrieval: April 10, 2024, https://patentsview.org/apis/api-endpoints/patents.

OpenAI (Aug. 2024). *Introducing GPTs*. [Online; accessed 22. Aug. 2024]. URL: https://openai.com/index/introducing-gpts.

Palikot, Emil and Matias Pietola (2022). "Pay-for-Delay with Settlement Externalities". In: *Working Paper*. URL: https://doi.org/10.1111/jems.12351.

Public Access to Court Electronic Records (2023). *Various Court Documents and Opinions*. Last accessed: February 2, 2024, https://pcl.uscourts.gov/pcl/pages/search/findCase.jsf.

Standard and Poor's (2024). *Compustat Financials Dataset*. Last accessed through WRDS: January 19, 2024, https://wrds-www.wharton.upenn.edu/pages/get-data/compustat-capital-iq-standard-poors/compustat/global-daily/security-daily/.

Unified Patents (2024). *Unified Patents Patent Portal*. Last accessed: April 12, 2024, https://portal.unifiedpatents.com/.

United States Patent and Trademark Office (2015). *Patent Historical Master File*. Last accessed: March 4, 2024, https://developer.uspto.gov/product/historical-masterfile.

— (2016). *Patent Litigation Dataset*. Last accessed: January 16, 2024, https://www.uspto.gov/ip-policy/economic-research/research-datasets/patent-litigation-docket-reports-data.

— (2024). *PatentsView API*. Last API retrieval: February 21, 2024, https://patentsview.org/apis/api-endpoints/patents.

US Department of Health & Human Services (2022). *Trends in Prescription Drug Spending*. Last accessed: February 3, 2024, https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf.